

### **REMARKS**

Claims 128-138, 202-205, and 339-344 are pending in the application. Claims 339-344 have been added. The Applicant notes with appreciation the allowance of claim 202-205.

#### **Rejections Under 35 U.S.C. §102(e)**

Claims 128-138 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,964,761 to Kambin ("Kambin"). The Applicant submits that this reference does not anticipate the subject matter of claim 128 under 35 U.S.C. §102(e).

#### **Independent Claim 128**

Claim 128 recites,

*A method for locating a preferred positioning for a prosthesis in a target implant location, comprising:*

*(a) locating a first plane within the target location in the transverse direction; and*

*(b) locating a second plane within the target location in the sagittal direction, wherein the first and second planes intersect to define a line along which a preferred position for locating the prosthesis can be determined.*

The PTO provides in MPEP §2131 that "[t]o anticipate a claim, the reference must teach every element of the claim." Therefore, with respect to claim 128, to support a rejection under 35 U.S.C. §102(e), the Kambin patent must contain all of the above claimed elements of the claim. As an initial matter, the Kambin reference does not teach "a preferred positioning for a prosthesis in a target implant location." The invention of Kambin is directed primarily toward "percutaneous *arthroscopic* disc removal, bone biopsy, and *fixation* of vertebrae" (Title), *not* prosthesis implantation. Furthermore, the Kambin reference does not teach or suggest "the first and second planes intersect to define a line along which a preferred position for locating the prosthesis can be determined." FIGS. 2 and 3 of Kambin and the associated text (col. 6, line 1-16) describe two dimensional perpendicularly arranged vertical and horizontal lines, not three

dimensional planes which intersect to define a line. Additionally, Kambin does not teach or suggest that the intersection of the vertical and horizontal lines is a preferred position for locating anything, particularly not a prosthesis. In fact, Kambin, which is directed toward vertebral fixation, teaches away from the Applicant's method for positioning a prosthesis. Therefore, the rejection is not supported by the Kambin reference and should be withdrawn.

Independent Claim 137

Claim 137 recites,

*A system for positioning instruments within a patient's intervertebral disc space relative to a reference line, comprising:*

*(a) a first instrument for locating and marking a transverse center of the disc space;*

*(b) a second instrument for determining a sagittal center of the disc space that intersects with the transverse center;*

*(c) an angle orienting instrument for adjusting the second instrument to be collinear with the reference line, which is positioned at a predetermined angle relative to a gravitational vector; and*

*(d) a machining fixture that is positioned with the second instrument relative to the reference line, and which is adapted to position additional instruments relative to the reference line.*

As provided by MPEP §2131, to support a rejection under 35 U.S.C. §102(e), the Kambin patent must contain all elements of this claim. However the cited text of Kambin fails to teach or suggest an instrument "positioned at a pre-determined angle relative to a *gravitational vector*" and also fails to teach or suggest "a machining fixture that is positioned with the second instrument relative to the reference line" Therefore, the rejection is not supported by the Kambin reference and should be withdrawn.

### Independent Claim 138

Claim 138 recites,

*A system for positioning instruments relative to a line during spinal surgery, comprising:*

*(a) a first instrument for determining a first point in a first plane and for indicating the position of the first point by marking a vertebral body;*

*(b) a second instrument adapted to be positioned relative to the mark for adapted for locating a second plane substantially perpendicular to the first plane, wherein the first and second planes intersect to form a line;*

*(c) a fixture adapted to be temporarily affixed to a vertebral body such that it is collinear with the reference line, and adapted to position site preparation instruments relative the line.*

As provided by MPEP §2131, to support a rejection under 35 U.S.C. §102(e), the Kambin patent must contain all elements of this claim. However the cited text and figures of Kambin fails to teach or suggest “a first instrument for . . . marking a vertebral body,” but instead discloses ink lines and entry point marks drawn *on the skin* of the patient’s back. (col. 6, lines 1-8)

Furthermore, as described above, Kambin teaches the intersection of two dimensional lines which intersect at a point, but does not teach or suggest “wherein first and second planes intersect to form a line.” Finally, as Kambin does not teach intersecting planes to form a line, it also does teach or suggest “a fixture . . . affixed to a vertebral body . . . and adapted to position site preparation instruments relative to the line [formed by intersecting first and second planes].”

Therefore, the rejection is not supported by the Kambin reference and should be withdrawn.

### Dependent Claims

Claims 129-136 depend claim 128 from and further define the method for locating a preferred positioning for a prosthesis, and therefore are also in condition for allowance.

### New Claims

New claim 339 recites, in part, “surgically exposing at least a portion of the space between the two vertebral bodies into which the articulable prosthesis will be placed” and inserting first and second tool into the space between two vertebral bodies. Kambin does not disclose or suggest the above elements or their interrelation. According to MPEP §2131, “[t]o establish a prima facie case of obviousness, . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations.” Accordingly, as the cited reference fails to disclose the elements of claim 339 as discussed above, claim 339 is allowable over the cited references. Dependent claims 340-344 depend from and further limit claim 339 and are allowable over the cited reference for at least this reason.

Appl. No. 09/923,891  
Reply to Office action of September 26, 2003

Attorney Docket No. 31132.69  
Customer No. 27683

### Conclusion

Therefore, it is respectfully submitted that independent claims 128, 137, 138, and 339 are in condition for allowance. Dependent claims 129-136 and 340-344 depend from and further limit independent claims 128 and 339, and therefore are allowable as well. Should the Examiner deem that any further amendment is desirable to place this application in condition for allowance, the Examiner is invited to telephone the undersigned at the below listed telephone number.

Respectfully submitted,



David M. O'Dell  
Registration No. 42,044

Dated: 12-16-03  
HAYNES AND BOONE, LLP  
901 Main Street, Suite 3100  
Dallas, Texas 75202-3789  
Telephone: 972/739-8635  
Facsimile: 214/200-0853

59696\_1.DOC

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

Date: 12-23-03  
By: Gayle Conner